

Message Text

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ACTION EB-06

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TO SECSTATE WASHDC 2989

INFO AMCONSUL GUAYAQUIL

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TAGS: BEXP, ECEM, BTRA, EC

SUBJECT: NEW PHARMACEUTICAL REGULATIONS

REF: A) STATE 224086, B) QUITO 6672, C) QUITO A-90

1. EMBOFF MET WITH ECONOMIST MARCOS GUARDERAS AND DR. GARCIA CONTRERAS REGARDING POINTS RAISED IN REF. A. GUARDERAS PREFERS PERIOD BEGINNING NOV. 18 FOR HIS VISIT TO THE U.S. SINCE HE WILL BE IN LIMA OCTOBER 29-31 ATTENDING THE ANDEAN PACT MEETING ON PHARMACEUTICALS. HE WOULD GO TO THE U.S. FOR APPROXIMATELY 12 DAYS AND SPEND THE FIRST 3 DAYS WITH FDA AND THE REMAINDER COULD BE DIVIDED BETWEEN PMA AND VISITS TO PRIVATE PHARMACEUTICAL COMPANIES. GUARDERAS WILL BE ONLY MINISTRY OFFICIAL GOING.

2. THERE ARE THREE GENERAL AREAS OF CONCERN TO GUARDERAS. THESE ARE: (A) DOCUMENTS AND REQUIREMENTS TO REGISTER COMPANIES TO PRODUCE PHARMACEUTICAL PRODUCTS (GOE REQUIRES THAT COMPANY FIRST APPLY FOR PERMISSION TO PRODUCE AND IS HAVING PROBLEMS IN REGISTERING COMPANIES AND ENFORCING ITS REQUIREMENTS), (B) THE SYSTEM USED TO REGULATE AND/OR FIX PRICES, (C) SANITARY AND TECHNICAL REGULATIONS FOR NEW PHARMACEUTICAL LABORATORIES.

3. GUARDERAS ALSO WISHES TO EXPLORE THE POSSIBILITY OF REACHING AN AGREEMENT WITH FDA WHEREBY IT COULD BE AN UNCLASSIFIED

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ARBITRATOR IN CONFLICTS BETWEEN THE PRIVATE ECUADOREAN-

BASED FIRMS AND THE MINISTRY OF HEALTH. THE PROBLEM, ACCORDING TO GUARDERAS, IS THAT GOE DOES NOT HAVE SUFFICIENTLY TRAINED PERSONNEL TO CONDUCT LABORATORY TESTS OR UNIT COSTS TO DETERMINE IF IT IS MAKING PROPER DECISIONS IN ENFORCING THE LAW. AN OPINION FROM A DISINTERESTED PARTY WOULD BE WELCOMED. THE U.S. FIRMS AFFECTED BY THE MINISTRY'S DECISIONS ARE MERCK SHARP & DOHME, SCHERING INTERNATIONAL, WARNER LAMPERT, PFIZER, AND PARKE DAVIS.

4. GUARDERAS AND CONTRERAS ALSO RAISED THE QUESTION OF POSSIBLE FINANCIAL ASSISTANCE IN THE WAY OF TRANSPORTATION, LODGING, AND MEALS FROM FDA OR PMA OR THE PRIVATE FIRMS WHICH THEY WOULD VISIT.

5. THE ONLY DOCUMENTS GUARDERAS WAS WILLING TO PROVIDE ARE THE HEALTH CODE, COPIES OF THE 1970, 1972, 1973 AND THE 1974 DECREES. A COPY OF THE DECREE GRANTING SMALL INDUSTRIES PREFERENTIAL TREATMENT WAS ALSO PROVIDED. THE EXISTING LAWS ARE COVERED IN THE 1973 DECREE AND THOSE SECTORS IN WHICH PROBLEMS HAVE ARISEN WERE MARKED BY GUARDERAS. THE 1974 DECREE IS SIMPLY A 90-DAY EXTENSION GRANTED TO THE FOREIGN FIRMS TO "CONDUCT STUDIES OF VARIOUS TYPES." THE DOCUMENTS IN SPANISH ARE BEING POUCHED AS PER INSTRUCTIONS WITH APPROPRIATED SECTIONS MARKED.
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